

Notice of Allowability

Application No.

09/489,711

Examiner

S. Devi, Ph.D.

Applicant(s)

ROBERTS ET AL.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 06/22/06.
2. ☒ The allowed claim(s) ~~is/are~~ 43-46, now renumbered as claims 1-4 respectively.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date 6/22/06
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

ATTACHMENT TO NOTICE OF ALLOWABILITY

Request for Continued Examination

1) A request for continued examination under 37 C.F.R 1.114, including the fee set forth in 37 C.F.R 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R 1.114, and the fee set forth in 37 C.F.R 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 C.F.R 1.114. Applicants' submission filed on 06/22/06 has been entered.

Applicants' Amendment

2) Acknowledgment is made of Applicants' amendment filed 06/22/06 in response to the final Office Action mailed 03/16/06.

Examiner's Amendment

3) An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to Applicants, an amendment may be filed as provided by 37 C.F.R 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee. The authorization to prepare this Examiner's amendment was provided by Mr. Timothy J. Gumbleton in a telephonic interview on 01 September 2006.

(A) The specification has been amended as indicated below:

The paragraph beginning on page 3, line 25 has been replaced with the following:

--In a preferred embodiment, the culture is inactivated by adding formalin (about 0.5% v/v final concentration). In another preferred embodiment, antigens of the invention are obtained from the supernatant or filtrate of an *E. rhusiopathiae* culture. A culture supernatant or filtrate, in a preferred embodiment, is concentrated about 10-fold and aluminum hydroxide gel (preferably REHYDRAGEL™) is added to the concentrated supernatant or filtrate at a final concentration of about 30% v/v to stabilize the antigen. In another preferred embodiment, a vaccine composition is formulated comprising the antigen and an adjuvant with the adjuvant comprising, for example, about 25% v/v of the vaccine composition. In another preferred embodiment, thimerosal (about 0.01% v/v final concentration) with EDTA (about 0.07% v/v final concentration) are added to the antigens as preservative. A preferred adjuvant, herein referred to as "No.1 Adjuvant", comprises about 2% v/v lecithin, about 18% v/v mineral oil, and about 8% v/v surfactant (e.g., about 5.6%

v/v TWEEN 80™, polyoxyethylene sorbitan monooleate, and about 2.4% v/v SPAN 80™, sorbitan monooleate), with the remaining volume being a saline solution (e.g., Dulbecco PBS). This adjuvant is described in U.S. Patent Application Serial No. 60/117,705, filed January 29, 1999, entitled "Adjuvants for Use in Vaccines", which is incorporated herein by reference.--

(B) Claims 17, 26, 27, 30-32 and 40-42 have been canceled.

(C) New claims 43-46 have been added as indicated below.

--Claim 43 (New). A vaccine composition comprising an antigen composition and an adjuvant composition, wherein the antigen composition comprises a fluid fraction of an *Erysipelothrix rhusiopathiae* culture and a stabilizing agent, wherein the *Erysipelothrix rhusiopathiae* culture is inactivated with beta-propiolactone or formalin and the stabilizing agent is aluminum hydroxide gel present at 30% v/v in said vaccine composition, and wherein the adjuvant composition comprises about 2% v/v lecithin, about 18% v/v mineral oil, and a combined volume of about 8% v/v of polyoxyethylene sorbitan monooleate and sorbitan monooleate surfactants with the remaining volume being a saline solution, wherein said vaccine composition is stable for at least one year and protects an animal against *Erysipelothrix rhusiopathiae* infection.

Claim 44 (New). The vaccine composition of claim 43, wherein the animal is a pig or weaned pig.

Claim 45 (New). The vaccine composition of claim 44, wherein the vaccine composition protects said weaned pig against *Erysipelothrix rhusiopathiae* infection for six months.

Claim 46 (New). The vaccine composition of claim 43, wherein the fluid fraction of the antigen composition is concentrated 6 to 20 fold.--

Status of Claims

4) Claims 17, 27, 30 and 32 have been amended via the amendment filed 06/22/06.

New claim 42 has been added via the amendment filed 06/22/06.

Claims 17, 26, 27, 30-32 and 40-42 have been canceled via this Examiner's amendment.

New claims 43-46 have been added via this Examiner's amendment.

Claims 43-46 are pending and are under examination.

Information Disclosure Statement

5) Acknowledgment is made of Applicants' information disclosure statements filed 6/22/06.

The information referred to therein has been considered and a signed copy is attached to this Office Action

Rejection(s) Moot

- 6) The rejection of claim 31 made in paragraph 18 of the Office Action mailed 03/16/06 under 35 U.S.C § 112, first paragraph, as containing new subject matter, is moot in light of the cancellation of the claim.
- 7) The rejection of claims 17, 26, 27, 30-32, 40 and 41 made in paragraph 18 of the Office Action mailed 03/16/06 under 35 U.S.C § 112, second paragraph, as being indefinite, is moot in light of the cancellation of these claims.
- 8) The rejection of claims 17, 26, 27, 30-32, 40 and 41 made in paragraph 19 of the Office Action mailed 03/16/06 under 35 U.S.C § 103(a) as being unpatentable over Frantz *et al.* (US 5,695,769 - already of record) in view of Applicants' admitted state of the prior art, Zarkasie *et al.* (*J. Vet. Med. Sci.* 58: 87-89, 1996, already of record) and Barenholz *et al.* (US 6,156,337 - already of record), is moot in light of the cancellation of these claims.

Relevant Art

- 9) The art made of record and not currently relied upon in any of the rejections is considered pertinent to Applicants' disclosure:
- US 20060173060 discloses TWEEN 80 to be polyoxyethylene sorbitan monooleate. See section [0252].
 - US patent 6,777,405 taught SPAN 80 to be sorbitan monooleate. See lines 28 and 29 in column 9.

Remarks

- 10) Claims 43-46, now renumbered as claims 1-4 respectively, are allowed.
- Claims 43-46 have descriptive support in the canceled claims 42, 27, 41, 40, 17 and 30; Examples 4 and 1-3; second full paragraph on page 9; and full paragraph on page 15 of the specification.
- 11) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Central Fax number, (571) 273-8300,

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which receives transmissions 24 hours a day and 7 days a week.

12) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

13) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Acting supervisor, Albert Navarro, can be reached on (571) 272-0861.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

September, 2006


S. DEVI, PH.D.
PRIMARY EXAMINER